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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,174	08/12/2005	Chuanzhong Wei	9907.8USWO	8380

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,174	WEI ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *6-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received July 6, 2007.

Election/Restrictions

Applicant's election without traverse of group I, claims 1-5 is acknowledged. Claims 6-9 are withdrawn because the claims are drawn to the non-elected invention.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

Acknowledgment is made for priority to a PCT/CN03/00378 and foreign priority document CHINA 02133567.2. The English translation of both documents the PCT/CN03/00378 and foreign priority document CHINA 02133567.2 has not been provided. As such the claims are granted the priority date of August 12, 2005.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/1/2005 in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner. It is noted that only the English abstracts of the Chinese documents have been considered.

Sequence listing

Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequence set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason (s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 – 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The specification discloses amino acid sequences in figure 3. However, these sequences are not identified by sequence identifiers in the brief description of the figures.

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE IF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filling a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extent the

period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice of Comply with the response.

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
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3. Hand Carry, Federal Express, United parcel Service or other delivery service to:
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Alexandria, VA 22314

Claim Objections

Claims 3-5 are objected to because the claims refer to sequences identified in I, II, III, and IV without reciting SEQ ID NO in the claims. Applicants are required to recite the sequence identifiers in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 recite the limitations "(...) characterized in that the BSE PrP antibody array consists of antibodies against normal and abnormal PrPs with N-terminal amino acid sequences identified in I, II, III, and IV respectively". It is not clear what Applicants are referring to by the recitation of identified in I, II, III, and IV. It is not clear if Applicants refer to tables, figures or Examples in the specification. Additionally it is not clear if Applicants intend to claim that the BSE PrP antibody must bind to the particular sequences within the prion protein or if Applicant is claiming that the sequences identified in I, II, III, and IV are within the PrP. In a situation when Applicant intends to claim that the antibodies must bind to the particular sequences the skilled artisan would be unable to determine which sequences must the BSE PrP antibody bind to. Therefore the metes and bounds of the claims cannot be determined. Clarification and correction is required.

Claims 2-5 recite PrP antibodies of 1-1000 nm, 100-150 nm, and 100-500 thick are immobilized on the electrodes. The specification does not define what kind of measurement Applicants intend to claim by referring to antibody thickness. The term "antibody thickness" is not used in the art of immunology or biochemistry. The skilled artisan would not know what kind of measurement is encompassed by the claimed antibody thickness. Correction and clarification is required.

Claim 1 recites "(...) antibodies are immobilized on the electrodes of the microelectrode array corresponding uniquely to the electrodes of the microelectrode array". The specification does not define what Applicants intend to claim by recitation of "corresponding uniquely". It is not clear what are the metes and bound of the unique correspondence of the antibodies to the electrodes of the microelectrode array recited in the claims. Correction and clarification is required.

Claim 2 recites "(...) the antibody array comprises antibodies against PrPs with various N-terminal amino acid sequences and in normal and/or abnormal configurations." The specification does not define the normal and abnormal configurations. The term "normal and abnormal configurations" with regard to the prion protein is not used in the art of prion chemistry. The skilled artisan would not know what is encompassed by the recitation of "normal and abnormal configurations." Correction and clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlstadter et al. (US Patent 6,673,533 B1).

Claims are drawn to a piezoelectric biochip for the detection of the bovine spongiform encephalopathy (BSE) pathogen, wherein piezoelectric biochip comprises a common electrode, which is fixed on the lower side surface of the piezoelectric biochip and a microelectrode array, which is fixed on the upper side surface of the piezoelectric biochip. The BSE prion antibodies are immobilized on the electrodes of the microelectrode array. The PrP antibodies are 1-1000 nm, 100-150 nm, and 100-500 nm thick. The BSE PrP antibody consists of antibodies against normal and abnormal PrPs with N-terminal amino acid sequences identified in I, II, III, and IV.

For the purpose of the present rejection the limitation of "BSE PrP antibody consists of antibodies against normal and abnormal PrPs with N-terminal amino acid sequences identified in I, II, III, and IV" is interpreted as the prion protein comprises amino acid sequences identified in I, II, III, and IV. Without guidance from the Applicants, with regard to I, II, III, and IV, Examiner interprets that Applicant refers to sequences recited in Figure 3. The sequences identified in I, II, III, and IV are considered to be comprised within the known prion protein. Therefore a disclosure reciting prion specific antibodies bound to the piezoelectric biochip anticipates the present claims.

Because it is unclear what kind of measurement Applicants refer to by reciting an antibody thickness, for the purpose of the present rejection the limitations with regard to an

antibody thickness are considered to represent the characteristics of an antibody that binds to prion protein.

Wohlstadter discloses a piezoelectric biochip, comprising an electrode and the microelectrode array, wherein the detection agents such as antibodies against prion protein are directly immobilized onto the electrode (see claims 1, 7-9, 30, and 53, column 22, lines 11-36, and 49-64, column 76, lines 65-67, and column 77, lines 1-12) Because Wohlstadter discloses the piezoelectric biochip wherein detection agents are antibodies against prions, Wohlstadter discloses piezoelectric biochip for the detection of the bovine spongiform encephalopathy (BSE) pathogen.

Thus by this disclosure Wohlstadter anticipates the present claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday between 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB
Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 9-4-07
Primary Examiner, TC1600

Notice to Comply	Application No. 10/523,174	Applicant(s) Wei et al.	
	Examiner Agnieszka Boesen Ph.D.	Art Unit 1648	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other See attached, see attached RAW SEQUENCE LISTING ERROR REPORT.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequence set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason (s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 – 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. APPLICANT IS GIVEN ONE MONTH FROM THE DATE IF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filling a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extent the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice of Comply with the response.

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